No. 94-1531

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

OCTOBER TERM 1994

NOVOPHARM, INC. and NOVOPHARM LTD.,

Petitioners,

—v.—

BURROUGHS WELLCOME CO.,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether the court below correctly held, based on its *de novo* review of the record, including several extensive offers of proof submitted by Petitioners, that Burroughs Wellcome Co. was entitled to judgment as a matter of law on its claim that United States Patent Nos. 4,724,232, 4,828,838, 4,833,130, 4,837,208 and 4,818,538 were valid and infringed by Petitioners.

IDENTIFICATION OF CORPORATE AFFILIATES PURSUANT TO RULE 29.1

Pursuant to Supreme Court Rule 29.1, Respondent Burroughs Wellcome Co. states that it is a North Carolina corporation and a wholly-owned subsidiary of The Wellcome Foundation Limited which in turn is a wholly-owned subsidiary of Wellcome, p.l.c. which was recently acquired by Glaxo, p.l.c. and which has changed its name to Glaxo Wellcome, p.l.c. All of the subsidiaries of Burroughs Wellcome Co. are wholly-owned.

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BRIEF IN OPPOSITION

Respondent Burroughs Wellcome Co. ("BW Co.") respectfully submits that a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit should not issue because no question worthy of the exercise of the Court's certiorari jurisdiction is presented and because the decision below is in all respects correct.

COUNTER-STATEMENT OF THE CASE

The Petition contains numerous misstatements and omissions with respect to both the course of the proceedings before the District Court and the opinion and holding of the

Court of Appeals. Such misstatements and omissions necessitate this counter-statement. *See* Supreme Court Rule 15.1.

This case concerns the validity and infringement of six United States patents owned by BW Co. covering compositions and methods for using the drug zidovudine (more commonly known as "AZT") to treat persons infected with the Human Immunodeficiency Virus ("HIV").[1] A.021.[2] BW Co. manufactures and sells AZT under the brand name Retrovir®. A.548. BW Co. alleged that Petitioners Novopharm, Inc. and Novopharm Ltd. (collectively, "Novopharm") infringed the BW Co. AZT Patents under 35 U.S.C. § 271(e)(2) (1988) as a result of Novopharm Ltd.'s June 26, 1992 filing of an Abbreviated New Drug Application with the United States Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic copy of Retrovir®. A.023. Shortly after they were filed, the actions against Novopharm, Inc. and Novopharm Ltd. were consolidated for discovery and trial with an identical action then pending against Barr Laboratories, Inc. ("Barr"). A.022-23.

During discovery, and in the Pre-Trial Order, both Novopharm Ltd. and Barr admitted to infringing the BW Co. AZT Patents[3] and conceded that each of the five named BW Co. inventors was properly named. A.13056; A.551. As a result, the trial focused on the assertion by Novopharm that

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[1] The patents at issue on this petition are No. 4,724,232, No. 4,828,838, No. 4,833,130, No. 4,837,208 and No. 4,818,538 (collectively, the "BW Co. AZT Patents").

[2] References to "Pet. App. __" are to the Appendix to the Petition for a Writ of Certiorari. References to "Pet. __" are to the Petition for a Writ of Certiorari. References to "A. __" are to the Record on Appeal.

[3] Novopharm, Inc. did not admit to infringing the BW Co. AZT Patents; the judgment entered against Novopharm, Inc. was vacated as premature by the Federal Circuit due to insufficient support in the record on this issue. Pet. App. 8a n.6. BW Co. submits that this is sufficient grounds for denying the Petition on behalf of Novopharm, Inc. *Penfield Co.* v. *SEC*, 330 U.S. 585, 589 (1947).

the patents were invalid and/or unenforceable because certain scientists at the National Institutes of Health ("NIH") had not been named as co-inventors (A.550-51); it was claimed that the positive results obtained from their blind screening of AZT against HIV *in vitro*[4] contributed to the conception of the invention. Pet. App. 9a-10a. The crucial question, therefore, was whether the BW Co. inventors' conception was complete prior to any work of the NIH scientists relating to AZT. Pet. App. 9a. This complete conception was evidenced and corroborated by a fully enabling draft patent application that was prepared before the NIH scientists conducted their blind screening of AZT. Pet. App. 16a-17a.

In order to conform their theory to the facts, therefore, Novopharm and Barr were forced to construct a novel standard for determining when there has been a completed conception. Ignoring over 100 years of precedent on this issue, they argued that a conception of an invention is not complete unless and until the putative inventor has a "reasonable expectation" that the invention will work. Pet. App. 12a. Thus, both Novopharm and Barr sought to prove that various experiments with AZT performed by and on behalf of BW Co. (including those testing the effect of AZT against animal retroviruses) were not "predictive" of how AZT would actually work in humans and, therefore, could not form the basis for a "reasonable expectation" that AZT would be an effective therapy for humans infected with HIV; only the results of the blind screening of AZT against HIV obtained by the NIH scientists, they contended, provided such a "reasonable expectation". Pet. App. 9a, 36a-37a.

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[4] An *in vitro* study is an experiment conducted entirely in a laboratory system (*i.e.*, a test tube), as opposed to an *in vivo* study which is conducted in a living being. The term "blind screening" refers to the fact that when the NIH scientists screened AZT, it was identified only as "Compound S"--they admittedly did not know the name or structure of the compound they were screening. A.933-34; A.15106-116.

BW Co. pointed out that the standard urged by Novopharm and Barr was *not* the law and that, accordingly, the evidence on predictivity that they proffered was wholly irrelevant. Pet. App. 37a. Immediately following the opening statements, after attorneys for Novopharm and Barr had explained what they expected the evidence to show, BW Co. moved for judgment as a matter of law, arguing that such evidence was legally insufficient to prove that the NIH scientists had contributed to the conception of the inventions disclosed in the BW Co. AZT Patents (A.676); BW Co. renewed this motion following certain in-court admissions by Barr's counsel after the District Court sustained BW Co. objections to the relevance of certain questions posed by counsel. A.13294-98.

Finally, after the District Court sustained a BW Co. objection to Barr's use of a chart entitled "The Mouse Test Is Not Predictive Of Human Responses," Barr's counsel admitted, for the sixth time,[5] that defendants could not under *any circumstances* prevail at trial if they were not permitted to inquire into the "reasonableness" of the beliefs of the inventors as to whether AZT would be an effective therapy for people infected with HIV or to inquire into the "predictivity" or lack thereof of the positive results of the BW Co. tests of AZT against murine [mouse] retroviruses. A.3048-60. The Court then solicited from counsel for all parties their views on how the case should proceed. Both Barr and Novopharm urged the Court to reconsider its ruling on the legal test for conception. However, both Barr and Novopharm conceded that if the Court maintained its ruling, they did not have sufficient evidence to go forward. A.3070; A.3162-64. Barr's counsel advised the District Court:

> "[the parties] are in agreement on this point, that this is a legal question and that if you should rule in their favor, . . . I should not be going forward. But I don't have

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[5] A.453-54; A.775-76; A.2401-03; A.13024; A.13027.

> any--I mean, I don't have it. It's not here. And when I finished, you would be directing a verdict against me."

A.3070. Novopharm's counsel did not object or disagree with this statement.

At this point, the District Court, turning to the pending BW Co. motions for judgment as a matter of law, directed the parties to file offers of proof relating to *any* matter the parties wished the District Court to consider. A.3095; A.3119-21; A.3145-46; A.3150-53; A.3159-62; A.3171.

Novopharm's criticisms of this use of the Rule 50(a) procedure by the District Court and the Federal Circuit are unfounded. First, Novopharm complains that it was "forced to be 'fully heard'." Pet. 4-5. However, Novopharm was allowed to submit three separate offers of proof comprising more than fifty pages each and accompanied by hundreds of pages of documents. Significantly, in neither its appeal to the Federal Circuit nor its petition to this Court, has Novopharm pointed to a single fact or piece of evidence missing from its offers of proof that it would have presented to the jury had the trial proceeded.

Second, Novopharm complains that the Rule 50(a) procedure denied it the opportunity to present its case to the jury. Pet. 4. But as the language of the rule and the Advisory Committee Note to the 1991 amendment made clear, entry of judgment under Rule 50(a) is appropriate at any time prior to the submission of the case to the jury when it becomes apparent that a party is unable to carry a burden of proof that is essential to its case. The rule does not require that a party be heard by a jury. Indeed, the rule is designed to avoid the necessity of a jury trial when resolution can be accomplished as a matter of law based upon undisputed facts. Novopharm could point to no evidence that could sustain its heavy burden of proof, and judgment as a matter of law was appropriate.

Following receipt of the offers of proof and further argument from counsel, the District Court, having determined that the parties were fully heard, recessed to review the submissions and consider the motion. The next day the District Court issued a 16-page opinion granting judgment as a matter of law to BW Co. Pet. App. 29a-44a. The Court held that:

> "The law of conception . . . is comprised of two elements. The first element relates to the state of mind of the inventor--whether he had a definite and permanent idea of the complete and operative invention. This element is subjective; so long as the idea is sufficiently defined and preserved, the law does not require that the inventor's idea be reasonable, scientifically accurate, or capable of being proved.
>
> * * *
>
> "The second element asked whether the inventor's idea, as defined and preserved, enables one of ordinary skill in the art to reduce the invention to practice. This element is objective."

Pet. App. 36a. The Court further held that "evidence concerning the reliability or predictiveness of the murine screens used by the BW Co. inventors . . . has no legal relevance." Pet. App. 37a. Thus, the Court concluded that, "[r]eviewing all of the evidence and resolving all inferences in favor of defendants," there was "no evidence which would enable the defendants to meet their burden of [clear and convincing] proof in this case."[6] Pet. App. 38a.

Novopharm appealed the judgment of the District Court to the Court of Appeals for the Federal Circuit, challenging the District Court's interpretation of the law of conception and its

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[6] In addition, the District Court held that, because the work of the NIH scientists was done at the direction and instruction of BW Co., they had acted merely as a "pair of hands" and, therefore, *could not* have contributed to the conception of the invention. Pet. App. 39a.

conclusion that there was no admissible evidence which would support a judgment for Novopharm. After a *de novo* review of the record, the Federal Circuit unanimously affirmed the District Court's judgment with respect to five of the six BW Co. AZT Patents.[7] Pet. App. 1a-28a. In so doing, the Federal Circuit, contrary to Novopharm's assertion (Pet. 6), completely validated the District Court's interpretation of the law of conception—using the same language and citing the same cases to reach a virtually identical conclusion. *Compare* Pet. App. 11a-16a, 19a *with* Pet. App. 36a-37a, 39a.

Novopharm's petition for rehearing was denied by the Federal Circuit on December 15, 1994. Pet. App. 45a. Novopharm did not seek rehearing *en banc*.

REASONS FOR DENYING THE WRIT

THE FEDERAL CIRCUIT'S DISPOSITION OF THIS CASE PURSUANT TO LONG-ESTABLISHED PRECEDENT RAISES NO ISSUE WORTHY OF THIS COURT'S CONSIDERATION

This case is a paradigmatic example of the type of appeal that is unworthy of the exercise of this Court's certiorari jurisdiction--a fact that is evident merely from reading the questions presented identified by Petitioner.

Despite the fact that both the District Court and the Federal Circuit have extensively reviewed the factual record in this case and both have concluded that BW Co. is entitled to judgment as a matter of law on the issue of inventorship with

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[7] The Federal Circuit, by a 2-1 majority, vacated the judgment with respect to U.S. Patent No. 4,818,750. Pet. App. 23a. The retrial concerning this patent is scheduled for October, 1995. In addition, *in dicta*, the Federal Circuit rejected the District Court's determination that the NIH scientists had merely acted as a "pair of hands." Pet. App. 18a.

respect to five of the six BW Co. AZT Patents, Novopharm would have this Court conduct yet a third review of the record to determine whether there is sufficient admissible evidence to create a factual question on the inventorship issue. Pet. 12-13. In particular, Novopharm requests that this Court review "the totality of the evidence", including the results of experiments with AZT conducted by the BW Co. inventors and by scientists at other institutions, as well as dozens (if not hundreds) of pages of documents reflecting the contemporaneous activities of BW Co., in order that this Court may second-guess the conclusions reached by both of the courts below concerning this evidence. Pet. 9-13. The factual review that Novopharm seeks, however, plainly is not deserving of a writ of certiorari.

Recognizing this fact, Novopharm attempts to portray the decision of the Federal Circuit as a "depart[ure] from the accepted and usual course of judicial proceedings." Pet. 7-8. In so doing, Novopharm inexcusably misreads the opinion below as having "rejected the district court's interpretation of the law of conception" and, based on a single passage quoted out of context, claims that the Federal Circuit "recognized that scientific accuracy and reasonableness, and the ability of the idea to be proved, bear on conception." Pet. 6. Thus, Novopharm concludes that the Federal Circuit committed an error worthy of review on certiorari by failing to consider "facts in Novopharm's offer of proof which bore directly on the issue of conception: experimental failures of others to show the activity of AZT against HIV, prior to the NIH's success, and the effect of those failures on the BW scientists' states of mind." Pet. 7.

A plain reading of the Federal Circuit's opinion, however, reveals the fallacy in Novopharm's contentions. The Federal Circuit, as had the District Court, held that:

> the test for conception is whether the inventor had an idea that was definite and permanent enough that one

> skilled in the art could understand the invention; the inventor must prove his conception by corroborating evidence, preferably by showing a contemporaneous disclosure. An idea is definite and permanent when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general research goal or research plan he hopes to pursue.

Pet. App. 11a (citation omitted); *see also* Pet. App. 37a-39a. Indeed, the Federal Circuit specifically rejected Novopharm's assertion that "scientific accuracy and reasonableness, and the ability of the idea to be proved, bear on conception" (Pet. 6):

> Novopharm suggest[s] that the inventor's definite and permanent idea must include a reasonable expectation that the invention will work for its intended purpose. . . . Without some experimental confirmation, they suggest, the inventor has only a hope or an expectation, and has not yet conceived the invention in sufficiently definite and permanent form. *But this is not the law*."

Pet. App. 12a (emphasis added).

Novopharm's interpretation of the Federal Circuit's opinion is based solely on a single passage from the opinion:

> A conception is not complete if the subsequent course of experimentation, especially experimental failures, reveals uncertainty that so undermines the specificity of the inventor's idea that it is not yet a definite and permanent reflection of the complete invention as it will be used in practice.

Pet. 6; Pet. App. 14a. To have any meaning, of course, the passage must be read in the context in which it appears--in this case, the context is a discussion of the inapplicability of simultaneous conception and reduction to practice cases. Pet. App. 13a-14a. In such cases, the invention is the result of trial and error research and the inventor cannot describe how to put the invention into practice until a successful experiment has

been performed. *Alpert* v. *Slatin*, 305 F.2d 891, 894 (C.C.P.A. 1962). The language upon which Novopharm relies does not, as Novopharm contends, mean that a specific and fully enabling conception of an invention ceases to be a conception when there is a subsequent experimental failure. The point of the language is that, in trial and error research, conception of a general goal is insufficient when the course of experimentation has not yet revealed to the inventor how the invention will be put into practice. In such a situation, the conception is not yet complete because the inventor is not in a position to make a disclosure of the invention that would enable its reduction to practice by one of ordinary skill. It is well established that,

> "conception has been achieved when 'the inventive idea is crystallized in all of its essential attributes and becomes so clearly defined in the mind of the inventor as to be capable of being converted to reality and reduced to practice by the inventor or by one skilled in the art.' *Technitrol, Inc.* v. *United States*, 440 F.2d 1362, 1369-70, 194 Ct. Cl. 596,609 (1971)."

Amax Fly Ash Corp. v. *United States*, 514 F.2d 1041, 1047 (Ct. Cl. 1975).

In this case, however, it was unnecessary to consider evidence of experimental failures by other scientists because evidence existed which completely corroborated the conception of the BW Co. inventors. Pet. App. 16a-17a. The Federal Circuit, as had the District Court, held that a February 6, 1985 draft British patent application "corroborates the claim that they had formulated a definite and permanent idea of the inventions by the time it was prepared." Pet. App. 16a; *see also* Pet. App. 38a-39a. Given this conclusion, Novopharm's assertion that the Federal Circuit should have considered evidence of purported experimental failures in determining inventorship is without merit and distorts the record.

Novopharm also attempts to create a certiorari-worthy dispute by mischaracterizing the Federal Circuit's opinion on the "pair of hands" issue as contrary to established law. Novopharm argues that "[o]nce the Federal Circuit held that the NIH scientists were more than a 'pair of hands,' it should have conferred joint inventor status to Drs. Broder and Mitsuya for contributing to the conception of the invention." Pet. 13. It further asserts that "[t]his is the first time that a contributor to an invention who has been found to be more than a mere pair of hands in reducing an invention to practice has not been afforded appropriate status as a coinventor. . . . It is simply not possible to be more than a pair of hands, i.e. to exercise inventive skill, without also being a joint inventor." Pet. 14.

Novopharm's argument is baseless. The assertion that one who, during the process of reducing an invention to practice, exercises skill greater than that of a pair of hands *ipso facto* makes an inventive contribution to the conception is without support in the caselaw. Indeed, the cases cited by Novopharm do not even suggest, let alone hold, that this equation is valid; these cases merely stand for the time-honored proposition that a conception is complete when one ordinarily skilled in the art can practice the invention without undue experimentation. *Sewall* v. *Walters*, 21 F.3d 411, 415 (Fed. Cir. 1994); *Land* v. *Dreyer*, 155 F.2d 383, 387 (C.C.P.A. 1946). Moreover, the question of whether the NIH scientists "exercised considerable skill" in the process of "simply confirming the operability of what the draft application disclosed" (Pet. App. 17a) is simply not relevant to determining whether the BW Co. conception was complete prior to that time. *Sewall*, *supra*, 21 F.3d at 415 n.3 ("the existence of research or experimentation does not necessarily indicate, by itself, that complete conception did not exist.") Indeed, as the Federal Circuit noted, "Novopharm concede[s] [that the draft patent application] would teach one skilled in the art to practice the inventions." Pet. App. 16a. Once a complete conception is

established, the question of whether the NIH scientists were a "pair of hands" is simply not material.[8]

CONCLUSION

The Petition for a Writ of Certiorari should be denied.

May 19, 1995

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[8] The inventions of the BW Co. AZT patents are directed to the treatment of patients, not the confirmation of activity in a test tube. Regardless of the skill required to perform the test tube procedure, it is undisputed that the BW Co. draft patent application contained sufficient detail to enable a skilled physician to treat a patient with AIDS or HIV disease. Therefore, the conception of the invention *as claimed* was complete before any NIH involvement.